

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The Effect of Saffron on semen analysis in infertile men after varicocelelectomy

Protocol summary

Summary

We conducted this study to determine the effects of saffron (*Crocus sativus*) on the results of semen analysis (semen volume, count, motility and morphology) after varicocelelectomy, probable side effects of saffron and assessment of NNT (Number To Treat) and CI (Confidence Interval) of 95% in the use of saffron. Based on previous studies, in this double blind clinical trial 60 nonsmoker 20 to 35 year old men without any systemic or urogenital disease (and history of childhood disease), or the use of approved drugs or illegal ones such as opioids, stimulants, hallucinogens and inhalants, or the history of testis trauma, that may affect the spermatogenesis and men without the history of prior varicocelelectomy, atrophic testis or FSH above the normal range will get selected and others will exclude. This study was approved by the ethics committee of Tabriz University of medical sciences. Men after complete interview and urological examinations and analysis of semen parameters will be operated and then will be administered 60mg saffron or placebo in similar capsules for 6 months. Saffron capsules will administer 3 times a week during the study course to 30 patients and placebo capsules like saffron capsules will administer to other 30 patients. Every disease, drug use or testicular trauma that may affect spermatogenesis or patient request results in exclusion of men during the study course. Semen analysis will again carry out and will compare with initial semen parameters in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403174181N8**

Registration date: **2014-04-10, 1393/01/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-10, 1393/01/21

Registrant information

Name

Yadollah Ahmadi AsrBadr

Name of organization / entity

Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 41 1329 1924

Email address

ahmadiy@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor of research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-04-05, 1393/01/16

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Saffron on semen analysis in infertile men after varicocelelectomy

Public title

The Effect of Saffron on semen analysis in infertile men after varicocelelectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Married men infertile with varicocele; Patients between 20 to 35 years; Non-smokers; Patients who are willing to participate in the study; Exclusion criteria: Smoking; Marijuana Patients consumer, Cocain, Alcohol and other, Patients with acute infections; Patients who have previously undergone surgery; Patients with unilateral testicular atrophy were; Patients with Azoospermia

Age

From **20 years** old to **35 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

vice chancellor of research, Tabriz University of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Postal code

5138665793

Approval date

2014-02-12, 1392/11/23

Ethics committee reference number

5/4/10354

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Effect of saffron on improvement of at least one of the parameters, morphology or motility of sperm

Timepoint

End of the treatment period of 6 months

Method of measurement

Experiment

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Placebo capsules contain a number, every other day, for six months

Category

Placebo

2

Description

Intervention group: daily 60-milligram capsules of saffron provided Bhamen approved by the Ministry of Health of Iran and Iran's national standard, every other day for six months a number

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra , Sina, Emam Reza, Hospital

Full name of responsible person

Dr.Yadollah Ahmadi AsrBadr

Street address

Alzahra Hospital, bagh-shomal; Artesh Street South;Azadi Avenue, Sina Hospital,University Avenue, Golgasht Street,Emam Reza, Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor of research, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

Golgasht Street; Tabriz University of Medical Sciences

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

vice chancellor of research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Yadollah Ahmadi AsrBadr

Position

Urology Physician, Associate

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty